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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,237	03/20/2000	Seth D. Rose	344-P-16-USA	9691

7590 07/13/2005

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/509,237

Applicant(s)

ROSE ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time and request for continued examination under 37 CFR 1.114, filed 04/26/05 and 04/25/05 respectively. Claim 9 is pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application and the submission filed on 04/25 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear whether hydrophobic group in part (2) of claim 9 is to be covalently or noncovalently attached to the water-soluble polymer. In addition, it is unclear whether said hydrophobic group in part (2) of claim 9 is a limitation of the water-soluble polymer or not, because of the future tense. It is unclear whether the hydrophobic group being used to modify the water-soluble polymer is the same as the hydrophobic group in part (3) of the claim or whether it is a different hydrophobic group. It is unclear where the hydrophobic group in parts (2) and (3) is. Is the hydrophobic group part of a polymer or a drug?

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claim 9 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Katada et al. (US 5,080,889).

Katada discloses a liquid cosmetic composition that has anti-inflammatory agents, vitamins and hormones incorporated therein (column 5, lines 52-59); another component in the composition is ethanol (column 5, line 42) and ethanol is a volatile solvent; still another component is a film forming material that would form a gel upon application (column 5, lines 60-64), which is carrier in Katada and which can be carboxymethylcellulose, polyvinylpyrrolidone and polyvinyl alcohol (column 6, lines 6-26).

The instant claim is directed to a method of forming a film in situ upon body tissues and the method comprises providing a volatile solvent, a polymer and a hydrophobic group; modifying the solubility of the polymer in the liquid by attaching the hydrophobic group to the polymer to produce a water-insoluble product; applying the liquid composition to the body tissue; evaporating the solvent from the liquid composition in situ to form a film that adheres to the body.

It is noted that the film forms upon evaporation of the solvent' and by this, the solubility of the polymer in the solvent of interest is modified and also when the polymer contained in the solvent is modified by the evaporation of the solvent, the hydrophobic group of the drug or active agent is attached to the polymer. Thus the method of the instant claims is disclosed by

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the prior art. However, in the alternative, evaporation of the volatile solvent would lead to the attachment of the hydrophobic group of the drug to the polymer. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the liquid cosmetic composition of Katada and to apply it to the skin, which will form a film upon the evaporation of the solvent. One having ordinary skill in the art would have been motivated to apply the formulation of Katada to the skin with the expectation of forming a film on the skin.

6. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller et al. (US 4,826,677).

Mueller teaches applying polymer dispersions containing medicines to skin to treat psoriasis. The liquid polymer solution polymerizes in situ to form a film as the solvent evaporates out of the solution or dispersion applied to the skin. The polymeric materials in Mueller are polyethylene, polyurethane, polyvinyl chloride, polyvinyl alcohols, polyvinyl acetate, polymethacrylates or mixtures thereof and methylcelluloses. Including functional groups through copolymerization with appropriate monomers produces cationic or anionic polymers. Urea is simultaneously present either in dissolved form or suspension. Antipsoriatic medicines such as allantoin, tar products, chrysarobin, dithranol, vitamin A and glucorticoids are some the medicinal agents incorporated in the film forming polymer composition (column 3, lines 9-18). See abstract, column 2, line 33-59, column 3, lines 9-44 and claims 1-12.

Mueller teaches the method of the instant claims except that Mueller does not teach the polymers recited in claims 9 and 12. However, Mueller suggests the use of mixtures or copolymers of polyethylene, polyurethane, polyvinyl chloride, polyvinyl alcohols, polyvinyl acetate, polymethacrylates as the polymer in the film forming polymeric composition (column 2,

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lines 54-57). Mueller also discloses the use of cellulose acetate, cellulose derivatives or methylcelluloses in the film forming polymeric composition (column 2, lines 57-59).

Although Mueller discloses cellulose derivatives as film forming polymer, Mueller does not specifically disclose carboxymethyl cellulose. Mueller does not also disclose hydroxyethyl cellulose or polyiminodiacetamide, which are the other film-forming polymer that is recited in claim 9. However, the person of skill or of ordinary skill in the art is aware that one film-forming agent can replace another and expect the composition to form a film upon application of the liquid formulation. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the film forming composition of Mueller onto body tissue so that the composition comprising polyethylene, polyurethane, polyvinyl chloride, polyvinyl alcohols, polyvinyl acetate, polymethacrylates or mixtures thereof and methylcelluloses and medicinal agents form a film over the body tissue. One having ordinary skill in the art would have been motivated to use substitute another film forming agent for the disclosed film forming agents, specifically a derivative of cellulose according to the disclosure of Mueller with the expectation that a film would form over the body tissue.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Marks (US 4,247,547) teaches a composition comprising a gel formulation that contains a therapeutically effective tretinoin, an organic solvent, hydroxyethylcellulose, hydroxypropylcellulose, BHT and BHA and vitamin E (abstract, column 2, lines 57-68 and column 3, lines 1-47). See also examples 2-13 for exemplification of some embodiments.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

